For the foregoing reasons, approval of revisions to figures 2A and 2B, and the withdrawal of the objection, are requested.

2. 35 U.S.C. §102 (Claims 47-54)

Claims 47-54 stand rejected under 35 U.S.C. §102 as anticipated by Frisch (US 4,100,246). Claim 47 is independent and claims 48-54 are dependent upon claim 47. Claim 47 has been revised to clarify that the configuration of the catheter is adjusted (e.g., by a physician) for a particular patient as opposed to being merely an industrial manufacturing method. The method steps now include (among other things) determining a desired configuration of catheter by reference to an individual patient; and implanting the catheter in the patient. Frisch does not show or suggest the claimed method.

For these reasons, the allowance of claim 47 and the claims depending therefrom are requested. The dependent claims specify additional features that are also believed to be patentable over the prior art.

3. 35 U.S.C. §103 (Claims 55-57)

Claims 55-57 stand rejected under 35 U.S.C. §103 as being unpatentable over Samson et al (US 5,462,523) in view of Frisch (US 4,100,246). Claim 55 is independent and claims 56-57 are dependent upon claim 55. Claim 55 has been revised to clarify that the configuration of the catheter is adjusted (e.g., by a physician) for a particular patient as opposed to being merely an industrial manufacturing method. The claimed method of manufacturing ***and implanting*** a catheter ***of customized configuration*** includes (among other things) the following steps: adjusting the length of the second tubular portion to conform to the dimensions of a selected site in an hippocampus or lateral ventricle ***of an individual patient***, and implanting the catheter for delivery of a therapeutic agent to the hippocampus or lateral ventricle. The Samson et al and Frisch patents, whether considered separately or together,[1] fail to show or suggest this claimed method.

[1] This discussion is without prejudice or admission with respect to applicant's right to challenge whether there is any incentive or suggestion to combine the references.

For these reasons, the allowance of claim 55 and the claims depending therefrom are requested. The dependent claims specify additional features that are also believed to be patentable over the prior art.

4. Double Patenting (Claims 47-58)

Claims 47-58 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-8 of US Patent No. 6,093,180. It is submitted that claims 47-58 as amended also obviate this rejection.

5. Double Patenting (Claims ~~47-58~~ 44-45)

Claims 44-45 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-8 of US Patent No. 6,093,180 and the Rogers et al article ("Clinical Trial of Indomethacin in Alzheimer's Disease"). Issue is taken with this rejection.

Absent hindsight based on the teaching of applicant's disclosure, there is no teaching, suggestion or motivation in Rogers et al to deliver indomethacin or other non-steriodal anti-inflammatory agents having cyclooxygenase inhibitor action locally in a lateral ventricle or hippocampus. Administering a drug orally does not suggest whether it would be advantageous or desirable to deliver the drug locally.

Rogers et al discloses that over 20% of patients treated with oral indomethacin developed drug related adverse effects that required their treatment to be discontinued and their removal from the study. Rogers et al also suggested that "gastroprotective measures should be considered in further trials of indomethacin or other NSAIDs" for Alzheimer's Disease, and "patients should be carefully monitored for gastrointestinal or other adverse effects."[2]

Rogers et al actually teach away from the claimed invention in that Rogers et al suggest attempting to remedy the stated problems with "gastroprotective measures" and "careful monitoring" rather than administering the drug to the hippocampus or left ventricle. **If, notwithstanding the problems stated in the Rogers et al reference, Rogers et al could only suggest greater care in orally administering indomethacin or**

[2] Rogers et al, at page 1610, Discussion in right hand column.

other NSAIDs, how can the claimed invention be considered obvious? In this regard, it may be worth noting that of the authors of the Rogers et al reference, four are listed as MDs and six are listed as having PhDs. (Two of the authors have MDs and PhDs.)

For these reasons, the double patenting rejection of claims 55-57 is believed to be obviated.

6. Miscellaneous and Conclusion

Enclosed herewith is an Amendment Transmittal that includes a petition for a three-month extension of time to respond to the Office Action dated October 3, 2001, thereby extending the response period until April 3, 2002. Authorization is provided to charge any fees required in connection with this paper, including fees for extension of time or new claims, to Deposit Account 13-2546.

In view of the foregoing, favorable reconsideration and allowance of this application are requested.

Respectfully submitted,

Date_____

By_____

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Version Showing Changes

Claim 47 (Once Amended). A method of making and implanting a catheter of customized configuration comprising the steps of:

providing a tubular body made of a tear resistant material that expands in the presence of a select external stimulus, the tubular body having a tubular body lumen with a diameter;

determining a desired configuration of catheter by reference to an individual patient;

exposing the tubular body to the external stimulus that causes the material of the tubular body to expand whereby the tubular body expands;

placing a tip in the tubular body lumen, the tip having an outside diameter at least equal to the inside diameter of the tubular body lumen when the tubular body is not exposed to the select external stimulus;

moving the tip relative to the tubular body to achieve [a] the desired configuration between the tip and the tubular body; [and,]

halting the exposure of the select external stimulus to the tubular body whereby the tubular body returns to its original size; and

implanting the catheter in the patient.

Claim 55 (Once Amended). A method of manufacturing and implanting a catheter of customized configuration comprising the steps of:

a) forming a first tubular portion of a relatively impermeable material, the first tubular portion formed having a lumen with a diameter;

b) forming second tubular portion of a porous material;

c) partially disposing the second tubular portion within the lumen;

d) adjusting the length of the second tubular portion to conform to the dimensions of a selected site in an hippocampus or lateral ventricle of an individual patient; [and]

e) establishing a near zero tolerance fit between the overlap of the second tubular portion and the first tubular portion; and

f) implanting the catheter for delivery of a therapeutic agent to the hippocampus or lateral ventricle.

65. (New) The method of claim 55 further comprising delivering a therapeutic agent with the catheter to treat Alzheimer's disease.

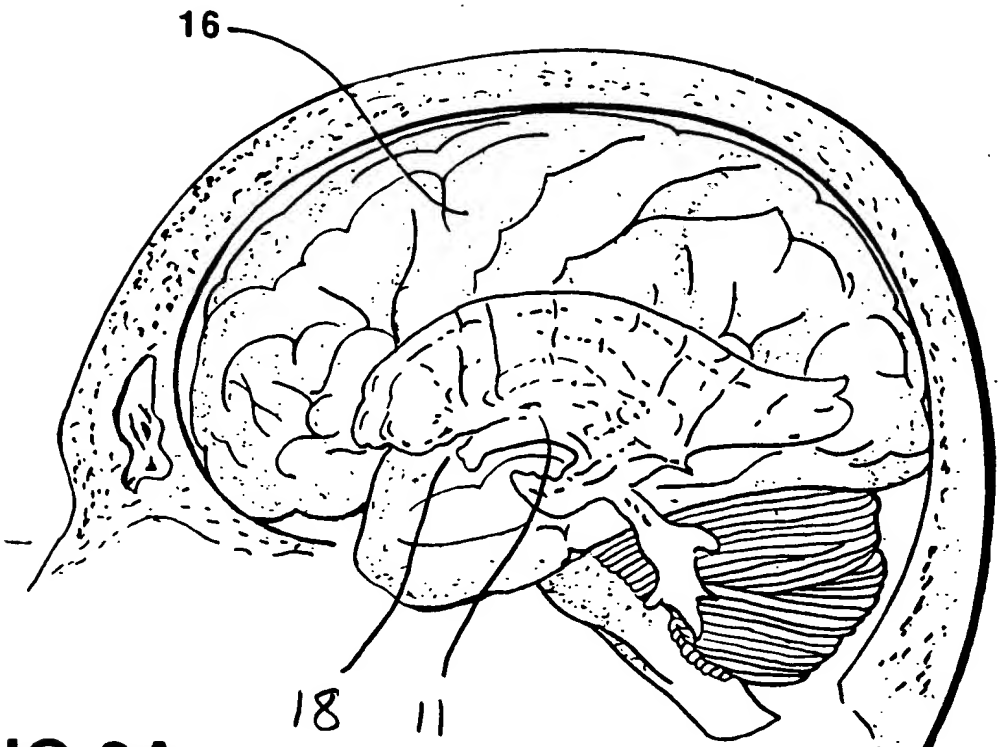
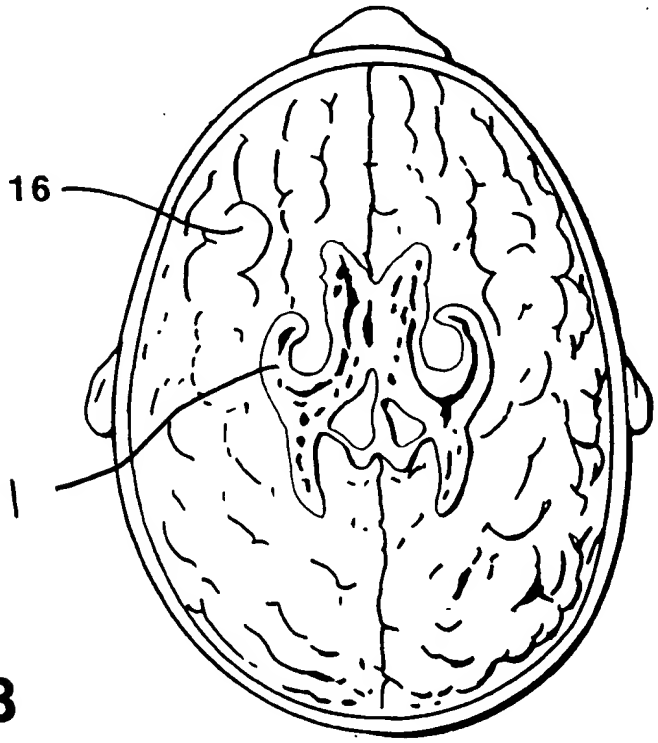


FIG.2A

Note



Note

FIG.2B

Approved
11/30/02